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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1698]

Food and Drug Administration Activities for Patient Participation in Medical Product Discussions; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; Establishment of docket; Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket for comments on FDA activities performed under the Food and Drug Administration Safety and Innovation Act (FDASIA), Patient Participation in Medical Product Discussions. This notice announces FDA's intent to gather input from stakeholders on strategies to obtain the views of patients during the medical product development process and ways to consider patients' perspectives during regulatory discussions. This notice provides background on ongoing patient engagement activities, so that stakeholders can consider both current and new activities that involve patient participation and perspectives during medical product regulatory discussions.

DATES: Although FDA welcomes comments at any time, to help FDA address issues related to Patient Participation in Medical Products Discussions in a timely fashion, comments should be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrea Furia-Helms, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5319, Silver Spring MD 20993-0002, Andrea.Furia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law FDASIA (Public Law 112-144). FDASIA expands the FDA's authorities and strengthens the Agency's ability to safeguard and advance public health in several areas including increasing stakeholder involvement in FDA regulatory processes. Specifically, section 1137 of FDASIA directs the Secretary of HHS to "develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and (2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry."

FDA has formed an Agency-wide working group to explore approaches and procedures as well as to align strategies across the Agency for patient participation in accordance with the statute. Involvement of the patient community brings the unique perspective of patients, family members, caregivers, and patient advocates to the decision-making processes of the FDA, and FDA is currently using a variety of tools to help ensure that the patient community is involved in medical product discussions to enhance benefit-risk assessment. FDA assesses the benefit-risk

of new drugs and certain devices on a case-by-case basis. In this assessment, FDA may consider, among other things, the degree of unmet medical need and the severity and morbidity of the condition or disease the drug or device is intended to treat or diagnose. This approach has been critical to increasing patient access to new treatments for cancer, other serious diseases, and rare diseases, where existing therapies have been few and limited in their effectiveness.

Currently, patient representatives can serve as Special Government Employees (SGEs) in order to participate as a member of an FDA's federal advisory committee meeting about medical products undergoing the FDA review process for marketing approval and other regulatory issues. Patient representatives serve as committee members on advisory committees managed by the Office of the Commissioner, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health. SGE patient representatives may also serve on special assignments to provide feedback and perspective on product reviews in progress. These SGE activities are in addition to the many other activities in which FDA obtains patient perspectives, such as open public hearings on specific diseases or drug development issues, and as speakers at FDA-sponsored conferences and workshops.

FDASIA includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biological products. This is the fifth authorization of PDUFA (otherwise known as "PDUFA V"), which was, as directed by Congress, developed in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. Under PDUFA V, FDA intends to conduct at least 20 public meetings that aim to more systematically gather patients' perspectives on their conditions and available therapies to treat those conditions (Patient Focused Drug Development).

PDUFA V also includes an initiative to enhance FDA's review of patient-reported outcome study endpoints and endpoint assessment tools.

FDASIA also includes the reauthorization of the Medical Device User Fee Act (MDUFA) that provides FDA the necessary resources to increase the efficiency of regulatory processes in order to reduce the time it takes to bring safe and effective medical devices to the U.S. market. This third authorization of MDUFA (otherwise known as "MDUFA III"), was a result of more than a year of public input, negotiations with industry representatives, and discussions with patient and consumer stakeholders. Under MDUFA III, FDA has established the Patient Preference Initiative to provide the information, guidance, and framework necessary to incorporate patient preferences on the benefit-risk tradeoffs of medical devices into the full spectrum of medical device regulatory processes and to inform medical device innovation by the larger medical device community. In the process, the initiative aims to advance the science of measuring medical device preferences of patients, caregivers, and providers. Once the Patient Preference Initiative helps to define or refine the methods to measure patient preferences, FDA intends to incorporate patient views into the total product life cycle of medical devices.

FDA is opening a docket for 30 days to provide an opportunity for interested stakeholders to submit comments on "strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions" under section 1137 of FDASIA. FDA is interested in comments on both current and new activities that would involve patient participation in regulatory discussions, as well as comments on ways to assess patient participation activities.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: October 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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